REMARKS

Applicants respectfully request reconsideration of the Examiner's objections and rejections of the claims in view of the following amendments and arguments.

Specification

The Examiner contends that the following "Application Nos." must be updated in reference to the applications' current status: WO2001/26545, EP1220640, and AU20007673-A. Applicants respectfully point out that these are *publication numbers* that each identify a specific publication of a foreign patent application. They cannot be updated and their status is immutable. They are in the nature of published technical articles, alluded to here by the Applicant for a source of how to obtain fetal ECG traces of acceptable quality, matter which is peripheral to the claimed invention.

Drawings

The Examiner noticed that in FIGURE 8, characters "81" and "82" should be switched. Accordingly, Applicant submits herewith a Replacement Sheet No. 8, containing FIGURE 8 and showing this correction. "ECG Data" is now labeled with 81, and "Event Data" with 82, to comport with the description thereof at page 16 of the Specification, lines 8 – 16.

Claim Objections

The Examiner objected to Claim 1 because of its recitation of "apparatus" rather than "an apparatus." Applicants respectfully traverse this ground for objection. "Apparatus" can denote

either one or many objects; the plural of "apparatus" is "apparatus". It is a word which should be read much as "machinery" or "instrumentation". Applicants' claimed scope of the invention should not be limited here to the singular or plural.

Claim Rejections – 35 USC § 112

The Examiner rejected Claims 2, 10, 29, 48 and 52 as indefinite for their recitation of "the maternal abdomen." To provide proper antecedent basis Applicants have amended Claim 1 to recite a "maternal abdomen" in substitution for a "maternal body."

The Examiner rejected Claims 6, 26, 43 and 51 for their recitation of "the QRS complex" in reference to the fetal ECG data. Applicants have amended these claims to recite "a QRS complex."

The Examiner rejected Claims 15 and 34 for their recitation of "the positive and /or negative energy" as having insufficient antecedent basis. These terms no longer exist in Claims 15 and 34 and hence this rejection is moot. It is believed that Claims 15 and 34 as amended are sufficiently definite and have proper antecedent basis.

The Examiner rejected Claims 16 and 35 because of their recitation of "the relative quantities" in reference to positive and negative energy. Applicants have amended Claims 15 and 34, from which claims 16 and 35 depend, to recite "relative proportions of energy of a fetal ECG complex waveform above and below a baseline reference." The addition of the "baseline reference" makes this recitation definite. Claims 16 and 35 now respectively further define this "baseline

reference" as the isoelectric line, which has a precise meaning in the art. See Applicants' Specification, p. 17, lines 8 – 10.

Claim Rejections – 35 USC § 101

The Examiner rejected Claims 1, 10, 40, 44 and their dependencies on the basis that the claimed invention is directed to non-statutory subject matter. To overcome this rejection the Applicants have adopted the Examiner's suggestion such that, in each of Claims 1, 10 and 40, "attached to a maternal body" has become "adapted to be attached to a maternal abdomen" (the amendment also curing a problem of antecedent basis, discussed earlier). Claim 44 has been amended to recite a preselected one of a plurality of electrode configurations *used in positioning* the electrodes on a maternal abdomen. It is believed that this functional recitation is enough of a conceptual division between what is claimed (the electrodes, and various configurations thereof) and what is not (the maternal abdomen).

Claim Rejections – 35 USC §§ 102 and 103

The Examiner rejected Claims 1 – 6, 22 – 26, 40 – 43, 45 – 47, 48 – 51 and 53 – 54 as allegedly anticipated by Nagel et al. US Patent No. 4,211,237 A ("Nagel"). The Examiner rejected the rest of the claims as obvious using Nagel as the primary reference and Marossero et al., US Patent Application Publication No. 2005/0267376 ("Marossero"), Beach et al., US Patent No. 5,088,498 ("Beach"), or Oriol et al., US Patent No. 5,596,993 ("Oriol"). Applicants respectfully traverse these grounds of rejection as applied to the claims as now amended.

Claim 1

The Examiner rejected Claim 1 as anticipated by Nagel, asserting *inter alia* that Nagel determines a number of fetal movements, citing Col. 11, lines 50 – 61 of that reference. Applicants must respectfully disagree. As used in this art and in Applicants' specification, "fetal movement" means either "fetal body movement" or "fetal breathing", not fetal cardiac contractions. Nowhere in Applicants' specification nor anywhere in the cited references does the term "fetal movement" consist of or comprise the beating of a fetus's heart.

To contend to the contrary doesn't make sense. Applicants do not use characteristics of a fetal heartbeat, to derive characteristics of a fetal heartbeat, in circular fashion. Rather, the Applicant uses characteristics of the fetal heartbeat to determine whether the fetus's body has moved or whether the fetus has demonstrated fetal episodic breathing. As discussed at page 10, lines 19 to 23 of the Specification, and as required by Claim 1, changes in the shape of the fetal ECG complex are used to detect fetal body movements. As further described in the Specification at page 11, lines 1 to 22, changes in the shape of the QRS complex between the various forms shown in Figures 5A to 5D are indicative of fetal body movements between the various positions represented by types A to D. Fetal movements, or 'events', are detected by transitions in the ECG shape to those shown in Figure 5 or intermediate shapes part way between (Specification, page 11, lines 13 to 19). "Recording the number and frequency of these transitions over a given recording period ... will provide a measure of fetal activity and hence an indication of fetal well-being" (*Id.,* lines 19 to 22).

None of the prior art teaches this technique.

Referring specifically to Nagel, this document teaches the use of an average fetal ECG waveform that is built up during an abdominal fetal and maternal ECG recording (see Column 5, line 54 *et seq*): "A cross-correlation function [is] derived from the abdominal signal S(t) and the sample EKG M(t). M(t) is the group average (average waveform) of the fetal EKG $E_f(t)$", or fetal template. The cross correlation is used to detect the fetal ECG.

Combinations of auto-correlation (AC) and cross-correlation (CC) allow an increased signal to noise ratio so that the fetal heart rate / frequency can be determined (Nagel, step 208, column 10, lines 47 to 50 and column 18, lines 1 to 8). Nagel uses ECG waveform shapes for CC processing but they are not used for the detection of fetal movements or fetal presentation.

More particularly, Nagel does not teach or suggest "an event logger determining from the determined differences [in the shapes of a succession of fetal ECG complex waveforms] a number of fetal movements during [a] period of time" as required by claim 1.

In fact, Nagel does not discuss "fetal movements", as this term is used by Applicants and others skilled in the art, at all. Although Nagel mentions "muscle movements which are a function of cardiac movements" (Column 11, lines 53 and 54), note that the present invention relates to fetal movements which comprise those which relate to motility of the fetus, e.g. fetal body and limb movements and fetal breathing movements (page 3, line 5). It is clear that cardiac muscle movements are not considered in this category not least because temporary accelerations in heart rate are widely recognised as an indicator of fetal movement (page 2, line 4) and therefore not "fetal movements" *per se*. Also, since conventional Doppler techniques used to assess fetal

movements (page 4, line 2 *et seq.*) actually exclude fetal heart rate frequencies (page 5, lines 4 to 10 and page 6, lines 7 to 26) it is clear that the person of ordinary skill in this art does not regard cardiac muscle movements as "fetal movements".

Still further, Nagel teaches away from the present invention in that the proposed technique could not work for such fetal movements. Nagel, Column 11, lines 48 *et seq.* states:

> "a rectifier ... is provided in the signal input so as to effect full wave rectification of the input signal without integration in a conventional circuit arrangement. This solution is of advantage during recording of myographic signals i.e. signals derived from muscle movements which are a function of cardiac movements, if the input signal to be detected has no fixed polarity. This results in the advantage, for use in recording the fetomaternal electrocardiogram, that the electrodes need not be placed in every case so that only positive or only negative peaks can be expected ..."

This is saying that as the heart pumps it produces myographic signals (i.e. ECG signals) which could either be positive or negative depending on the position of the electrodes. Hence if one rectifies the signal then the resulting signal is always positive. Once a signal is rectified then detection of fetal movements that result in changes in shape towards either positive or negative ECG's will be lost.

Claims 2 – 6

These claims are patentable at least for their dependency on allowable Claim 1.

Claims 7 – 11

These claims stand rejected over a combination of Nagel and Marossero, the Examiner pointing in particular to Marossero's Paragraph 183: "Templates of simulated fetal waveforms

corresponding to different fetal presentations in the uterus are then presented to an input-output matching means." But Marossero nowhere discloses or suggests the detection of fetal movements, as all of Claims 1 – 21 require. Nor is there any teaching, suggestion or motivation that Nagel and Marossero be combined, as the former continuously updates a single fetal ECG complex store. This average complex is computed by using a weighted average (referred to as "exponential averaging" – equation 4, Col. 14, line 31) of typically the last 16 fetal complexes; the averaging constant U (=16) is referred to at Nagel, Col. 19, line 66. Nagel makes no attempt to discriminate one fetal complex from another based on a possible difference in fetal position, but simply averages them all.

Claim 8 (as well as Claims 10, 29, 44, 47 and 54) have been amended to more clearly point out that as claimed by these claims, a preselected one of a plurality of possible electrode configurations is related to a corresponding set of ECG templates. These amendments are supported at least by p. 15, lines 17 – 25 of the Specification. Marossero does not contemplate more than one electrode configuration; Para. 61 of that reference discloses precisely one such configuration and the reference does not address the possibility of others. Claim 9 is additionally patentable because of its recitation of the event logger recording occasions on which the determined template changes – something which neither Nagel nor Marossero attempt to do.

Claims 12 – 14

These claims stand rejected over a combination of Nagel and Beach. The Examiner points in particular to Beach, Col. 4, lines 5 – 11, for the teaching of the use of a phase detector to determine the approximate phases for *ultrasounds* reflected at different depths. But Beach does

not concern itself at all with maternal/fetal *ECG* complexes or the analysis of same, and in any event does not disclose or suggest how fetal movements can be detected from such phase changes.

Claims 15 – 21

These claims stand rejected over a combination of Nagel and Oriol. The Examiner points to Oriol's teaching, at Col. 9, lines 60 – 67 and Figure 5A thereof, of a time plot of a baseline heart rate signal, in which the plot shows decelerations associated with loss of variability. What Oriol does not show or suggest is the detection in change of relative proportions of energy of a fetal electrocardiogram complex (not heart rate in beats per minute, but, within a segment of an ECG identified as a complex, ECG signal amplitude over time). Oriol superimposes a range of fetal heart rates on the graph in Fig. 5A, not a baseline from which relative proportions of energy above and below this line can be derived. Nor does Oriol disclose or suggest how differences in the shapes of fetal ECG complexes can signal fetal movement, and indeed does not attempt to analyze such complexes at all. Relative to Claim 20, the "warning" indication showing in Figure 13's display is not related to whether a determined number of fetal movements during a period of time, which itself has been derived from fetal ECG complex data, falls below a predetermined threshold.

Claim 22

Independent Claim 22 corresponds to independent claim 1 and is distinguished over Nagel for reasons similar to those discussed above in connection with claim 1, namely that it does not

teach or suggest determining, from ECG data, a number of fetal movements within a predetermined period of time.

Claims 23 – 26

These claims, dependent on independent Claim 22, are allowable at least for the reasons that Claim 22 is allowable.

Claims 27 – 30

These claims stand rejected based on a combination of Nagel and Marossero. Neither reference discloses or suggests determining, from ECG data, a number of fetal movements. And, given Nagel's averaging of all recent received ECG complexes and storing the result, it is impermissible to combine the two, as Nagel teaches away from storing separate templates based on different fetal presentations. Claim 28 is further patentable in that neither of these references discloses or suggests the determination of when the determined template changes. Claim 29 is further patentable because Marossero only teaches a single electrode configuration (Marossero, Para. 61) and does not contemplate that there might be several such, or that a set of predetermined fetal ECG templates might be selected according to which one of these is used.

Claims 31 – 33

These claims stand rejected based on a combination of Nagel and Beach. They are patentable for the reasons expressed relative to claims 12 – 14: The Beach ultrasound disclosure does not deal with the analysis of ECG data at all, and neither reference discloses or suggests the determination of a number of fetal movements.

Claims 34 – 39

The Examiner rejected these claims as obvious in view of a combination of Nagel and Oriol. They are patentable for the reasons expressed relative to Claims 15 – 21. Oriol does not attempt to derive information from ECG complexes at all. Per Claim 34, the range of beats per minute which Oriol superimposes on a graph of fetal heart rate does not at all disclose or suggest the ascertainment of a baseline reference, in relation to which relative proportions of energy of a fetal ECG complex waveform, can be calculated. It does not show or suggest the use of an isoelectric line, per Claim 35; nor, per Claim 36, that this reference is derived from a previous or average ECG waveform; nor, per Claim 39, an alarm when a determined number of fetal movements per unit of time (which had been ascertained through the analysis of ECG data) falls below a predetermined threshold.

Claim 40

The Examiner suggests that Column 3, line 42 of Nagel teaches "Apparatus for determining fetal spatial presentation and/or position" as recited in claim 40. Applicants respectfully submit that neither this indicated passage nor anything else in Nagel supports this assertion. Applicants can find no teaching in Nagel at all that relates to determining fetal spatial presentation and/or position. The examiner further asserts that Column 3, lines 39 to 50 of Nagel teaches "a memory storing a plurality of fetal ECG templates each corresponding to a specific fetal spatial presentation and/or position" as recited in claim 40. Applicants can find no such teaching at all. At most, Nagel appears to suggest storing a sample fetal ECG signal for comparison with a later sample. The stored sample will correspond to some unknown fetal spatial presentation and/or

position; there is no teaching or suggestion of storing a plurality of templates each corresponding to a specific (i.e. known) spatial presentation. Also, to the extent that the template of Nagel is an average template, it could not have any meaningful relationship with a specific fetal spatial presentation. In fact, Nagel preprocesses the data (as by "rectifying" it, as previously discussed) in ways which teach away from identifying and storing such separate templates.

Therefore, it will also be clear that the comparator in Nagel does not compare each received waveform with a set of such templates each corresponding to a specific fetal spatial presentation.

Claims 41 – 43, 45 -- 47

The Examiner rejected these dependent claims as allegedly anticipated by Nagel when taken alone. At least for the reasons expressed in relation to Claim 40 from which they depend, these claims are allowable over the art of record. Relative to Claim 47, since Nagel does not have the ability to store anything but an averaged ECG complex, it will not be able to store templates each one of which corresponds to a fetal spatial presentation and a specific electrode configuration.

Claim 44

The Examiner rejected Claim 44 as made obvious in view of a combination of Nagel and Marossero. The latter reference recites, at Para. 183, "templates of simulated ECG waveforms corresponding to different fetal presentations in the uterus are then presented to an input-output matching means. In one embodiment, each template is correlated (or "matched") with the raw data at the location of the fetal QRS Complex. Accurate fetal presentation is provided by the

highest correlation coefficient." This treatment is in contrast to what happens to the raw data in Nagel. In Nagel the fetal heart signal, regardless of shape, is averaged exponentially and stored in an average memory. The circuitry averages at least seven, and up to sixteen, fetal QRS complexes in arriving at a reference signal for a cross correlation function. Nagel, Col. 19, lines 49 – 62. Necessarily, during this averaging function all distinctions relating to change in shape in the QRS complex are lost, and therefore all ability to determine whether such a complex indicates any one particular fetal presentation or orientation. In Nagel, there is no resultant detected fetal QRS complex, identified as such, to compare against one of several prestored templates, and no way to attain these differentiated templates to begin with. As such, there is insufficient teaching, suggestion or motivation to combine these very different fetal ECG signal processing apparatus. Lastly, neither Nagel nor Marossero contemplates that there might be more than one electrode configuration which a clinician can select, or that a set of stored fetal ECG templates may correspond to such a selection.

Claim 48

Claim 48, rejected as anticipated by Nagel, is a method claim which corresponds in its essential distinguishing structure to apparatus Claim 40, and is allowable over Nagel for the same reasons. Nagel does not disclose or suggest storing a set of templates each corresponding to a predetermined electrode configuration; instead, Nagel only stores an average fetal ECG complex. Therefore, claim 48 distinguishes over Nagel for the same reasons given for claim 40.

Claims 49 – 51, 53 -- 54

These dependent claims are allowable not least by virtue of their dependence on independent Claim 48. Relative to Claim 54, Nagel does not disclose or suggest a plurality of different electrode configurations, in which each template corresponds to a specific fetal presentation and position and a specific one of a plurality of possible electrode configurations,

Claim 52

Claim 52 stands rejected in view of a combination of Nagel and Marossero. Claim 52 recites the selection of a set of predetermined fetal ECG templates according to a configuration of ECG electrodes positioned on the maternal abdomen. Marossero does not disclose or suggest the possibility of several electrode configurations; in fact, Marossero at Para 61 discloses only one such configuration (of eight electrodes in all) and does not contemplate how any of several different configurations might be alternatively employed. Further, as described above, Nagel teaches away from comparing a signal to a series of stored templates.

Conclusion

The foregoing discussion shows how the claims as now amended patentably define over Nagel, either alone or in combination with any of the secondary references relied upon by the Examiner, and the rest of the prior art. Since all other rejections and objections of the Examiner have been overcome, Applicants respectfully request the Examiner to issue an early Notice of Allowance.

This Reply to Examiner's Action is being submitted with a fee for a first month's extension of time. Applicant's amendments do not necessitate the payment of additional claim fees. Nonetheless, the Commissioner is hereby authorized to charge Deposit Account No. 503982 of Momkus McCluskey, LLC to cover any fee deficiency.

Respectfully submitted,

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